DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express

Our Reference: 29-52786

November 23, 1999

Fernando M. Mattos
Managing Partner
Mattos Brothers Dairy
4017 Kansas Avenue
Hanford, California 93230

WARNING LETTER

Dear Mr. Mattos:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on October 20 and 21, 1999, by Food and Drug Administration (FDA) Investigator Robert J. Anderson have revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On August 26, 1999, you consigned a cow (identified by USDA Domestic Laboratory Report No. 401823) to be slaughtered for human food. This cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this cow revealed sulfadimethoxine in the liver at 14.00 parts per million (ppm) and in the muscle at 4.90 ppm. Presently, the tolerance level for sulfadimethoxine in the uncooked edible tissues of cattle is 0.10 ppm. The USDA analysis also revealed penicillin in the liver at 0.28 ppm. Presently, the tolerance level for penicillin in the uncooked edible tissues of cattle is 0.05 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful

drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring that drugs are used in a manner consistent with the directions contained in their labeling.

4. You lack an adequate system for assuring that animals are treated with drugs which have been approved for use in their class of animal or species.

5. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug Albon brand of sulfadimethoxine within the meaning of Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of Section 201(v) and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling. Labeling for Albon specifies a dosage of two boluses per 1,000 - 1,200 pounds of body weight to be given on the first day and one bolus each day on the second through the fifth days of treatment. Labeling also specifies a seven-day withdrawal period prior to slaughter. Your practice of administering three boluses each on the first and second days of treatment, coupled with an inadequate withdrawal time, is likely the cause of the illegal residue found in the aforementioned cow.

You are adulterating the drug Agri-Cillin brand of penicillin G procaine within the meaning of Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of Section 201(v) and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling. Labeling for Agri-Cillin specifies a dosage of 1 milliliter (ml) per 100 pounds of body weight and not more than 10 mls per injection site. Your practice of administering 15 mls into one injection site is not in conformance with approved labeling.

You are adulterating the drug OXY-MYCIN 100 brand of oxytetracycline hydrochloride within the meaning of Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of Section 201(v) and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling.

Labeling for OXY-MYCIN 100 states that the drug is for intravenous use only and not for use in lactating dairy cattle. Your practice of infusing OXY-MYCIN into the udders of lactating dairy cattle, for the treatment of mastitis, is not permitted unless it is by or on the order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and compliant with Title 21 Code of Federal Regulations (CFR) part 530.

You are adulterating the drug RXV Tetracycline 324 Powder brand of tetracycline hydrochloride within the meaning of Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of Section 201(v) and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling. Labeling for RXV Tetracycline specifies that it is for use in drinking water for treatment of swine, calves, chickens, and turkeys. Your practice of intrauterine insertion of gelatin capsules containing RXV Tetracycline into your dairy cows is not permitted unless it is by or on the order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and compliant with Title 21 Code of Federal Regulations (CFR) part 530.

Your failure to comply with the label instructions on drugs used to treat your animals presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Your firm has established a history of offering cull cows and calves for sale for human food use which have been found to be adulterated with drug residues. According to USDA analytical reports, during the period of January 20, 1993, through August 27, 1999, you sold five cows for food use which were found to contain illegal drug residues. In addition, during this same time period you sold one calf for food use which was found by USDA analysis to be FAST positive due to the possible presence of harmful levels of antibiotics. An inspection was conducted of your dairy on April 12 and 15, 1996. During the inspection you were warned that it is illegal to market animals with illegal levels of antibiotics. A Warning Letter, dated April 19, 1996, was

sent to you as a result of the violations found during the inspection. Also, USDA sent you a letter for each instance in which their analysis found violative levels of drug residues. You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, please notify our Fresno office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Robert J. Anderson, Investigator, United States Food and Drug Administration, 2202 Monterey Street, Suite 104E, Fresno, California 93721.

Sincerely yours,

Patricia C. Ziobro

Patricia C. Ziobro
Director
San Francisco District

cc: Jose L. Mattos
Partner
Mattos Brothers Dairy
4017 Kansas Avenue
Hanford, California 93230

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